EXHIBIT 2

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP., Plaintiff, v. BLUEWILLOW BIOLOGICS, INC., ROBIN ROE 1 through 10, gender neutral fictitious names, and ABC CORPORATION 1 through 10 (fictitious names). Defendants.	Case No. 2:21-cv-10312-SJM-RSW Hon. Stephen J. Murphy, III

PLAINTIFF'S OPENING TECHNICAL REPORT

Dr. Eward A. Leomo

Dr. Edward A. Lemmo
60 Gilroy Street
Staten Island, NY 10309
(718) 967-3426
edlemmo@gmail.com

June 27, 2022

Stanley H. Kremen, Esq.
4 Lenape Lane
East Brunswick, NJ 08816

RE: Trutek Corp. *v.* BlueWillow Biologics, Inc.
Civil case No. 2:21-cv-10312

Dear Mr. Kremen:

You engaged my services to investigate allegations of infringement of Trutek's U.S. Patent No. 8,163,802 by BlueWillow's Nanobio Protect product that was purportedly on sale between January 2020 and April 2021.

My qualifications to perform this investigation are as follows:

I received a B.S. degree in Chemistry in 1973 from St. Francis College in Brooklyn, New York, and both an M.S. and Ph.D. in Nutrition Science in 1977 and 1979, respectively, from Rutgers University in New Brunswick, New Jersey. My resume is attached to this report as Exhibit A.

As part of my previous professional activities, I evaluated patent disclosures and claims both in an employment and consulting capacity. I am familiar with patents. I am familiar with, and I have worked with nanoemulsions, the technology upon which Nanobio Protect relies. I am also acquainted with the technology upon which Trutek's patent is based. I researched a number of scientific articles, and I relied upon reports produced by Dr. Alexei Ermakov and Shane Burns. The materials and scientific articles that I reviewed are listed in Exhibit B.

I hereby submit the following report of my investigation for your review.

Very truly yours,

Edward A. Lemmo

Edward A. Lemmo

TABLE OF CONTENTS

LIST OF EXHIBITS

FINDINGS AND CONCLUSIONS

1. BlueWillow's Nanobio Protect product is sold in the form of a liquid that is administered into a user's nasal passages.

2. The claims of Trutek's '802 Patent recite a method for nasally administering a formulation and for the formulation itself. The formulation of Trutek's '802 Patent is administered in and around a user's nasal passages.

3. BlueWillow's Nanobio Protect product exhibits an electrostatic charge, and once applied, creates an electrostatic field that extends from the skin or tissue of the user's nasal passages.

4. The formulation of Trutek's '802 Patent claims exhibits an electrostatic charge. Once applied, the formulation creates an electrostatic field in the vicinity of the user's nasal passages.

5. BlueWillow's Nanobio Protect product forms a thin film in the user's nasal passages. The thin film adheres to the skin or tissue of the user's nasal passages.

6. Trutek's '802 Patent claims that its formulation forms a thin film in and around the user's nasal passages. The thin film adheres to the skin or tissue of the user's nasal passages.

7. The formulation of BlueWillow's Nanobio Protect product contains at least one cationic agent. A cationic agent creates a positive electrostatic charge. According to BlueWillow's published literature and the Nanobio

Protect product packaging, the formulation contains benzalkonium chloride, Benzalkonium chloride is a known cationic agent.

8. The formulation of BlueWillow's Nanobio Protect product contains at least one biocidic agent or biocide. A biocidic is a substance that destroys or inhibits the growth or activity of living organisms. According to BlueWillow's published literature and the Nanobio Protect product packaging, the formulation contains benzalkonium chloride, Benzalkonium chloride is a known biocidic agent.

9. The Nanobio Protect product comprises nano-droplets that electrostatically attract and hold "germs" (*i.e.,* harmful particles). The nano-droplets further contain benzalkonium chloride (a known biocide), which renders the "germs" harmless.

10. Claims 1 and 2 of the '802 Patent recite a formulation that electrostatically attracts and holds harmful particles and renders them harmless.

11. The Nanobio Protect product reads upon the '802 Patent's method claim 1 when it is administered nasally because its formulation forms a thin film that it (1) adheres to the skin or tissue of the user's nasal passages; (2) electrostatically attracts harmful particulate matter; (3) holds the harmful particulate matter; and (4) inactivates the harmful particulate matter, and renders it harmless.

12. The Nanobio Protect product reads upon claim 2 of the '802 Patent's formulation because it (1) is intended to be applied to the skin or tissue of the user's nasal passages; (2) forms a thin film that adheres to the skin or

tissue of the user's nasal passages; (3) comprises at least one cationic agent; (4) comprises at least one biocidic agent; (5) electrostatically attracts harmful particulate matter; (6) holds the harmful particulate matter; and (7) inactivates the harmful particulate matter, and renders it harmless.

13. The Nanobio Protect product reads upon claim 6 of the '802 Patent because it contains benzalkonium chloride, which is a cationic agent.

14. The Nanobio Protect product reads upon claim 7 of the '802 Patent because it contains benzalkonium chloride, which is a biocidic agent.

RESULTS OF INVESTIGATION

I. DISCUSSION

In conducting my investigation, I read and understood:

- the complaint filed on February 10, 2021,
- Trutek's U.S. Patent No. 8,163,802 ("the '802 Patent"),
- a report prepared by Alexei Ermakov on January 11, 2021,
- a report prepared by Shane Burns of Electro-Tech Systems ("ETS") on January 18, 2021,
- copies of the portion of the BlueWillow website (*www.bluewillow.com*) relating to the Nanobio Protect product, which was in existence on January 7, 2021.
- information on the Nanobio Protect product packaging,
- U.S. Patent Nos. 8,226,965, 8,703,164, 9,131,680, 9,144,606, 9,492,525, 9,561,271, 10,206,996, 10,525,121, 10,596,251, all of which were assigned by the inventors to Nanobio Corporation[1], and
- several articles relating to nanoemulsions appearing in prominent scientific publications.

2. THE '802 PATENT

The '802 Patent was issued to Ashok Wahi on April 24, 2012, and assigned to Plaintiff, Trutek Corp. ("Trutek"). It was allowed to issue from a non-provisional patent application filed on May 16, 2009. The application was published by the USPTO on January 7, 2010. The earliest priority date of the

[1] BlueWillow Biologics, Inc. ("BlueWillow"), a Delaware corporation, is the successor to Nanobio.Corporation, a Michigan corporation.

'802 Patent Is July 7, 2008. The '802 Patent will expire on March 28, 2030. The '802 Patent is attached to this report as Exhibit C.

The '802 Patent has twenty-three claims. Claims 1, 2, and 8 are independent claims. Claims 3-7 are dependent claims that depend from claim 2. Claims 9-23 are dependent claims that depend from claim 8. A dependent claim incorporates all of the limitations from its base claim by reference. For example, when trying to understand claim 3, one must first understand claim 2, and see claim 3 as further limiting claim 2. Independent claims are broad and generic. Dependent claims are limiting and specific. Based on my knowledge and experience, all of the claims of the '802 Patent were easy for me to understand from a technical standpoint.

The Complaint asserts that three claims (*i.e.,* claims 1, 2, and 7) are infringed. That means that the allegedly infringing product reads on those claims (*i.e.,* the product does what the claim recites). In my opinion, claim 6 should be added to the list, because the product also reads on claim 6.

Unfortunately, discovery in this case has not yet revealed all of the ingredients in the formulation of the Nanobio Protect product. Thus, I was not able to ascertain whether the Nanobio Protect product reads on any of the other claims. Thus, I confined my investigation to comparing the Nanobio Protect product with claims 1, 2, 6, and 7 of the '802 Patent. However, should further information about the Nanobio Protect product ingredients become available, I reserve the privilege of supplementing my report.

a. CLAIM 1

Claim 1 is a method claim. It does not recite a manufactured product. Instead, it recites a method of electrostatically preventing a user from being infected by harmful particles by applying a formulation to the skin or tissue of the user's nasal passages. Once applied, the formulation forms a thin film or substrate that adheres (or sticks) to the skin or tissue of the user's nasal passages. The adhesion of the thin film can be adjusted by addition of a thickener. However, even without a thickener, the thin film will adhere to the skin or tissue.

Once applied, the formulation exhibits a static electrical charge, and it creates an electrostatic field in the vicinity of the skin or tissue. The thin film attracts oppositely charged harmful particles within the vicinity of the electrostatic field and in close proximity to the substrate. The thin film captures and holds the particles. An ingredient in the formulation that inactivates the harmful particles and renders them harmless.

b. CLAIM 2

Claim 2 is a claim for a formulation intended to be applied to the skin or tissue of a user's nasal passages. The ingredients of the formulation are recited generically, and their concentrations are adjusted to provide specific characteristics. Among the ingredients of the formulation are at least one cationic agent and at least one biocidic agent. However, additional ingredients are not excluded.

Once applied, the formulation possesses a static electric charge, which creates an electrostatic field in the vicinity of the user's nasal passages. When applied, the formulation forms a statically charged thin film. The cationic agent in the thin film produces a positively charged electrostatic field in the vicinity of the nasal passages. Negatively charged harmful particles (including living microorganisms) are electrostatically attracted to the thin film. Ingredients in the formulation adjust the adhesion of the thin film so as to capture and hold the harmful particles. Ingredients in the formulation adjust the cohesion of the thin film to provide adequate impermeability. The biocidic agent in the formulation functions to inactivate or inhibit the captured harmful particles so as to render them harmless.

c. CLAIM 6

Claim 6 is a dependent claim, which depends from claim 2. Thus, claim 6 recites a formulation having all of the same characteristics and limitations of claim 2. However, it is further limited by reciting that benzalkonium chloride is among the cationic agents in the formulation. Benzalkonium chloride is a well known cationic agent. It produces a positively charged electrostatic field.

d. CLAIM 7

Claim 7 is a dependent claim, which depends from claim 2. Thus, claim 7 recites a formulation having all of the same characteristics and limitations of claim 2. However, it is further limited by reciting that benzalkonium chloride is among the biocidic agents in the formulation. Benzalkonium chloride is a well known biocide.

3. NANOEMULSION TECHNOLOGY

Based on my education and experience, I am very familiar with technology associated with, *inter alia*, nanoemulsions, surfactants, adjuvants, electrostatic charges, cationic agents, biocidic agents, biocides, and preservatives.

Nanoemulsions are oil-in-water emulsions that are stabilized by emulsifying agents. They are also referred to as ultrafine emulsions. They exist as extremely small sub-micron sized droplets. Nanoemulsions are widely used in applications such as food products, cosmetics, and pharmaceuticals. Nanoemulsions may be engineered to improve the biological accessibility of bioactive molecules that are either entombed within them or maybe consumed alongside them. Nanoemulsions exhibit remarkable droplet stability due to their nanoscopic dimensions. By their very nature, nanoemulsion droplets exhibit an electrostatic charge which causes them to repel one-another. If the nanodroplets are not electrostatically charged, they would coalesce into a single liquid mass.

4. THE NANOBIO PROTECT PRODUCT

Nanobio Protect was manufactured and sold as a "nasal antiseptic solution" by BlueWillow. I understand that the product was discontinued sometime around April 2021, and that It is no longer being sold. The front of the product packaging is shown in the above photograph. As may be observed, the product contains "benzalkonium chloride (0.13%) antiseptic." The product claims to "kill 99.9% of germs." As an added claim, it "persists on skin for 4+ hours." On the rear of the product packaging, benzalkonium chloride is listed as the active ingredient.

Trutek, the owner of the '802 Patent, manufactured and sold a product named NasalGuard Airborne Particle Blocker, both the formulation of which and the nasal administration of which were protected by the '802 Patent. BlueWillow's Nanobio Protect product was sold in the same online and retail venues as Trutek's NasalGuard product. They competed with one another.

On January 11, 2021, Dr. Alexei Ermakov prepared a report describing his experimentation that compared electrostatic charges produced on paper substrates by Nanobio Protect, NasalGuard Misting Spray, and NasalGuard Airborne Particle Blocker products. Dr. Ermakov's report is separately produced for discovery. I reviewed this report and found Dr. Ermakov's methodology and conclusions to be sound. Dr. Ermakov concluded that all products exhibited an electrostatic charge of the same order of magnitude. I relied on Dr. Ermakov's work in forming my opinions.

On January 18, 2021, Shane Burns of Electro-Tech Systems (ETS) prepared a report describing his experimentation that compared charges

produced on pig skin substrates by Nanobio Protect and NasalGuard Misting Spray products. The use of pig skin is more predictive than paper regarding how the product would behave on human skin. Notwithstanding, Mr. Burns reached the same conclusion as Dr. Ermakov. The electrostatic charges exhibited by both products were of the same order of magnitude. Mr. Burns' (ETS) report is separately produced for discovery. I reviewed this report and found Mr. Burns' methodology and conclusions to be sound. I relied on Mr. Burns' work in forming my opinions.

Copies of a portion of the BlueWillow website (*www.bluewillow.com*) from February 7, 2021 relating to the Nanobio Protect product are attached to this report as Exhibits D and E. On Page 2 of Exhibit D, the following statements are made by BlueWillow:

> *The unique effectiveness of NanoBio Protect is derived from BlueWillow's patented nanotechnology. NanoBio Protect places the BZK antiseptic[2] on the surface of nano-droplets, which results in at least four key advantages:*
>
> 1. *The nano-droplets are attracted to germs by electro-kinetic charge and present the BZK in such a way to enable killing of germs on contact.*
> 2. *The droplets persist on skin for 4 or more hours, enabling long lasting effectiveness.*
> 3. *The droplets significantly hydrate skin to avoid dryness and cracking that can allow germs in.*
> 4. *And lastly, when bound to nano droplets, BZK is non-irritating to the skin.*
>
> *NanoBio Protect kills germs via membrane disruption. Nanobio Protect is comprised of positively charged droplets that are 300-600 nm in size. the droplets are attracted to negatively charged germs in the skin.*

[2] "BZK" is BlueWillow's abbreviation for benzalkonium chloride.

Here, the Nanobio Protect product is a liquid nanoemulsion consisting of nano-droplets that range between 300-600 nanometers in size (*Id.*). These droplets are extremely small. A nanometer is one-billionth of a meter. When administered to a user's nostrils, the product forms a thin film that adheres to the skin or tissue of his nasal passages. If that were not the case, the liquid would instantly drip out of the user's nose. Instead, "the droplets persist on the skin for four or more hours." Further, the "droplets significantly hydrate skin to avoid dryness and cracking that can allow germs in." Thus the product exhibits impermeability.

The product is cationic (*i.e.,* positively charged). Most harmful microorganisms are anionic (*i.e.,* negatively charged). The formulation contains benzalkonium chloride (a cationic agent) as its active ingredient. The positively charged thin film of nano-droplets inside the user's nostrils electrostatically attracts the negatively charged microorganisms. According to BlueWillow, the germs are "bound" to the nano-droplets. Therefore, they are held in place by the formulation. Finally, the benzalkonium chloride (a biocidic agent) "kills germs via membrane disruption."

Therefore, the Nanobio Protect product reads upon the '802 Patent's method claim 1 when it is administered nasally because its formulation forms a thin film that (1) adheres to the skin or tissue of the user's nasal passages; (2) electrostatically attracts harmful particulate matter; (3) holds the harmful particulate matter; and (4) inactivates the harmful particulate matter, and renders it harmless.

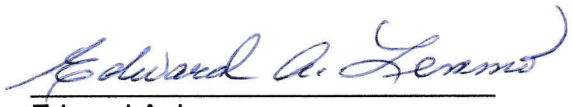
Further, the Nanobio Protect product reads upon claim 2 of the '802 Patent's formulation because it (1) is intended to be applied to the skin or tissue of the user's nasal passages; (2) forms a thin film that adheres to the skin or tissue of the user's nasal passages; (3) comprises at least one cationic agent; (4) comprises at least one biocidic agent; (5) electrostatically attracts harmful particulate matter; (6) holds the harmful particulate matter; and (7) inactivates the harmful particulate matter, and renders it harmless.

Finally, the Nanobio Protect product reads upon both claims 6 and 7 because its formulation contains benzalkonium chloride, which is both a cationic agent and a biocidic agent.

SUMMARY

As a result of my investigation, I concluded that the Nanobio Protect Nasal Antiseptic Solution marketed and sold by BlueWillow reads on claims 1, 2, 6, and 7 of the '802 Patent. Moreover, that product performed the same functions and competed with Trutek's NasalGuard Airborne Particle Blocker, which is protected by the '802 Patent.

Respectfully submitted,



Edward A. Lemmo

EXHIBIT A

Edward A. Lemmo, Ph.D.
60 Gilroy Street
Staten Island, New York 10309
(917) 837-1470
Email: edlemmo@gmail.com

EDUCATION

Ph.D. Nutrition Science, Rutgers University, New Brunswick, NJ (1979)
M.S. Nutrition Science, Rutgers University, New Brunswick, NJ (1977)
B.S. Chemistry, St. Francis College, Brooklyn, NY (1973)

EXECUTIVE TRAINING COURSES

Executive Leadership Program, Princeton, NJ
Time Management Skills, Teaneck, NJ
Media Communication Skills, New York City, NY

EMPLOYMENT EXPERIENCE

2007-Present **Consumer Healthcare Corporate Consultant**
Self-employed Consultant - Consumer Healthcare

2005-2007 **BioBalance Corporation**, New York, NY
Vice President, Product Development

Person primarily responsible for investigating its probiotic product PROBACTRIX™ to be used for treating pouchitis and other gastrointestinal disorders. Probiotic products are an optional alternative to the probiotic Lactobacillus acidophilus. In charge of all scientific product evaluation conducted at company headquarters.

1999-2005 **Wyeth Consumer Healthcare**, Leonia and Madison, NJ
Vice President, Product Development

Division of American Home Products
Formerly Whitehall-Robbins Consumer Healthcare

Managed product development for SOLGAR®, and contributed towards CENTRUM®, and CALTRATE®, brands. Responsible role in scientific affairs and new business

development opportunities. Further, responsible for evaluation of acquisition of new business entities.

1992-1999 **General Nutrition Centers, Inc.**, Pittsburg, PA
Director, Nutritional Sciences

Analyzed safety of amino acid products for presentation to the FDA and FTC and other U.S. government agencies. Evaluated and made recommendations regarding nutritional and homeopathic products. Performed quality assurance activities related to label claims and product safety. Responsible for introduction of the new PRO-PERFORMANCE sports nutrition product line into the GNC retail marketplace.

In 1993, for Quigley Corporation, I evaluated the safety and efficacy of Cold-EEZE® zinc lozenges to be used to shorten a common cold as a possible line of homeopathic products exclusively marketed by GNC.

1989-1992 **Pall Biomedical Products**, Glen Cove, NY
Marketing Manager

Responsible for marketing activities of Intravenous filtration devices, and Heat and Moisture exchange respiratory products. Wrote all scientific evaluation documents related to Heat and Moisture Exchange respiratory product for presentation to anesthesiologists regarding prevention of injury from patients breathing cold dry gas during surgery. Developed scientific presentations, videos, and product marketing material for use by healthcare professionals.

1984-1989 **ICN Pharmaceuticals**, Costa Mesa, CA
Director of Nutritional Technology

Faraday Laboratories Division

Product development of nutritional supplements for use by chiropractic and alternative health practitioners throughout the United States and Canada. Product brands included Nutridyn® and Sivad Bioresearch®. Responsible for new product development, wrote technical literature, and prepared and delivered scientific educational presentations to practitioners at chiropractic colleges and chiropractic meetings.

1976-1977 **Pharmacia Laboratories**, Piscataway, NJ
Clinical Trials Coordinator

Assisted veterinarian in analysis of equine blood samples. Performed evaluation analysis of HEALON® products comprising hyaluronic acid, and their effect on tissues.

CORPORATE CONSULTING EXPERIENCE

2011 **Matrixx Initiatives, Inc.**, Princeton, NJ
Scientific Affairs Consultant

Performed research associated with ZICAM® oral zinc product. Provided guidance for coordinating research trials. Managed human efficacy clinical trials.

1998-1999 **Church & Dwight**, Princeton, NJ
Scientific Advisor

Evaluated consumer healthcare products. Explored and determined market for magnesium based organo-metalic agents for use in dietary supplements.

1998-1999 **IVC Industries**, Freehold, NJ

IVC is a contract manufacturer of generic vitamins. Responsible for new product development. Assisted the marketing staff with product label claims.

1996 **Nutrition 21**, Purchase, NY

Company is a supplier to GNC. Performed consulting work regarding their products.

1996 **Nutramerica**, Lincoln Park, NJ

Technical advisor for the development of a dietary supplement product line.

CORPORATE CONSULTING EXPERIENCE (continued)

1996 **American Vitamin**, Ramsey, NJ

Company is a contract manufacturer. Performed new product development and assistance with evaluation of raw materials from India.

COLLEGE TEACHING EXPERIENCE

2013-2018 **Touro College,** New York City, NY

Taught in nursing school.Courses included pathophysiology, genetics, anatomy and physiology and tutored microbiology

2008-2014 **University of Medicine & Dentistry of New Jersey (UMDNJ)**, Newark, NJ

Taught innutrition program. Courses includedgeneral chemistry, anatomy and physiology, biochemistry, and microbiology.

1977 and **New York University,** New York, NY

2000-2003 Taught in graduate nutrition program, vitamin and mineral metabolism

2011-2012 **Cedar Crest College**, Allentown, PA

Taught courses in nutritional biochemistry and metabolism.

1984-1989 **University of New Haven**, West Haven, CT

Taught graduate level course in vitamin and mineral nutrition.

1974-1984 **Brooklyn College, CUNY**, Brooklyn, NY
Assistant Professor

Taught nutrition courses to pre-medical and nutrition students.

1973-1977 **Rutgers University**, Piscataway, NJ

Taught general biology lab and mineral metabolism.

EXHIBIT B

MATERIALS REVIEWED FOR REPORT PREPARATION

1. the complaint filed on February 10, 2021,
2. Trutek's U.S. Patent No. 8,163,802 ("the '802 Patent"),
3. a report prepared by Alexei Ermakov on January 11, 2021,
4. a report prepared by Shane Burns of Electro-Tech Systems ("ETS") on January 18, 2021,
5. copies of the portion of the BlueWillow website (*www.bluewillow.com*) relating to the Nanobio Protect product, which was in existence on January 7, 2021.
6. information on the Nanobio Protect product packaging,
7. U.S. Patent Nos. 5,618,840, 5,853,763, 5,951,970, 7,314,624, 8,226,965, 8,703,164, 9,131,680, 9,144,606, 9,492,525, 9,561,271, 10,206,996, 10,525,121, and 10,596,251.
8. U.S. Patent Application Publication No. 2007/0036831 A1.
9. Schulman, J.H., *et.al.*, "Mechanism of Formation and Structure of Micro Emulsions by Elecron Microscopy," J. Phys. Chem. 1959, 63, 10, 1677-1680, Publication Date: October 1, 1959.
10. Peek, L.J., *et.al.,* "Nanotechnology in Vaccine Delivery," Advanced Drug Delivery Reviews 60 (2008) 915-928, published February 2008
11. Rosano, H.I., *et.al.*, "Microemulsions: A commentary on their preparation," J. Soc. Cosmet. Chem., 39, 201-209, (May/June 1988).
12. Martins, S., *et.al.*, "Lipid-based colloidal carriers for peptide and protein delivery – liposomes versus lipid nanoparticles," Int'l Jour of Nanomedicine, 2007:2(4) 595-607.

13. Yaghmur, A., *et.al.*, "Phase behavior of microemulsions based on food-grade nonionic surfactants: effect of polyols and short-chain alcohols,"

EXHIBIT C

US008163802B2

(12) **United States Patent**
Wahi

(10) **Patent No.: US 8,163,802 B2**
(45) **Date of Patent: Apr. 24, 2012**

(54) **ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION, PRODUCT, AND METHOD**

(75) Inventor: **Ashok Wahi**, Hillsborough, NJ (US)

(73) Assignee: **Trutek Corp.**, Hillsborough, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 316 days.

(21) Appl. No.: **12/467,271**

(22) Filed: **May 16, 2009**

(65) **Prior Publication Data**

US 2010/0004337 A1 Jan. 7, 2010

Related U.S. Application Data

(60) Provisional application No. 61/085,855, filed on Aug. 3, 2008, provisional application No. 61/078,478, filed on Jul. 7, 2008.

(51) **Int. Cl.**
A61K 31/198 (2006.01)
A61K 31/14 (2006.01)

(52) **U.S. Cl.** **514/564**; 514/643

(58) **Field of Classification Search** 514/564, 514/643; 128/206.11
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

1,071,015	A	8/1913	Adler
2,237,954	A	4/1941	Wilson
2,433,565	A	12/1947	Korman
2,751,906	A	10/1953	Irvine
2,777,442	A	1/1957	Zelano
3,145,711	A	8/1964	Beber
3,513,839	A	5/1970	Vacante
4,030,491	A	6/1977	Mattila
4,052,983	A	10/1977	Bovender
4,267,831	A	5/1981	Aguilar
4,401,117	A	8/1983	Gershuny
4,789,504	A	12/1988	Ohmori et al.
4,874,659	A	10/1989	Ando et al.
5,468,488	A	11/1995	Wahi
5,674,481	A	10/1997	Wahi
6,844,005	B2	1/2005	Wahi
2003/0223934	A1	12/2003	Wahi

Primary Examiner — Raymond Henley, III
(74) *Attorney, Agent, or Firm* — Stanley H. Kremen

(57) **ABSTRACT**

A product to reduce and method of reducing the risk of inhalation of harmful substances by applying a formulation composition to a substrate or the skin in close proximity of one or more nostrils. This formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful.

23 Claims, No Drawings

ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION, PRODUCT, AND METHOD

CROSS REFERENCE TO RELATED APPLICATIONS

a) The Present application is the non-provisional counterpart of my pending U.S. Provisional Patent Application Ser. No. 61/085,555 (the '555 application) filed on Aug. 3, 2008 which is incorporated by reference in its entirety herein. The Present application claims the benefit of and priority to said '555 application.

b) The Present application is also the non-provisional counterpart of my pending U.S. Provisional Patent Application Ser. No. 61/078,478 (the '478 application) filed on Jul. 7, 2008 which is incorporated by reference in its entirety herein. The Present application claims the benefit of and priority to said '478 application.

c) The Present application is likewise related to my prior U.S. Provisional Patent Application Ser. No. 60/570,103 (the '103 application) filed on May 12, 2004 (now expired), and which is incorporated by reference in its entirety herein. The '478 application provides a virtually identical disclosure to the '103 application.

d) Furthermore, the Present application is related to my pending U.S. Provisional Application Ser. No. 61/078,472 filed on Jul. 7, 2008, which is incorporated by reference in its entirety herein.

e) The Present application is also related to my prior U.S. Provisional Patent Application Ser. No. 60/598,462 filed on Aug. 3, 2004 (now expired), and which is incorporated by reference in its entirety herein.

f) The Present application is additionally related to my U.S. Pat. No. 5,468,488, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT AND METHOD" issued on Nov. 21, 1995. This patent is incorporated by reference in its entirety herein.

g) The Present application is further related to my U.S. Pat. No. 5,674,481, entitled "ELECTROSTATICALLY CHARGED NASAL TOPICAL APPLICATION PRODUCT" issued on Oct. 7, 1997. This patent is incorporated by reference in its entirety herein.

h) The Present application is moreover related to my U.S. Pat. No. 6,844,005 entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH" issued on Jan. 18, 2005. This patent is incorporated by reference in its entirety herein.

i) Finally, this application is furthermore related to US Non-Provisional Utility patent application Ser. No. 10/082,978 entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH" filed on Feb. 25, 2002. This patent application is incorporated by reference in its entirety herein.

FIELD OF THE INVENTION

The Present Invention relates to the field of protective compositions against assault by various irritants and noxious substances as well as against assault by assorted microorganisms that typically gain entry into the body through the airway and/or nasal mucosa. The Present Invention also relates to anti-viral, anti-bacterial, and anti-microbial products and methods that involve the use of products heretofore developed for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. This reduced the inflow of airborne contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body. In the present invention, these electrostatically charged nasal application products capture and hold the contaminants including viruses, bacteria, and other harmful microorganisms or toxic particulates, inactivate them dermally outside the body and render them harmless.

BACKGROUND OF THE INVENTION

The nasal passages and nasal mucosa serve as body entry points for a wide variety of noxious and toxic substances. The body's immune system responds with certain relatively harmless irritants to the nasal passages and airways with reflex responses such as coughing and sneezing. This merely reintroduces the irritants into the environment. However, when the irritant comprises microorganisms, especially those that reproduce within the body and that are transmitted by coughing and sneezing, others may become infected. When a person feels a cough or a sneeze coming on, he merely covers his nose and mouth. However, if that person is contagious, this action does little to prevent others from also becoming infected. Furthermore, the use of a tissue or handkerchief for this purpose is extremely inefficient. This limits the protection of an individual from becoming infected or infecting others.

Other means of dealing with preventing inhalation of harmful or irritating substances or of infections agents include wearing facemasks to filter out these irritants. An example of this is the simple dust mask, typically found in the hardware store or medical supply store. However, even these are inadequate and inefficient. In many localities, during flu season, one can see a large number of people wearing these dust masks in public places. The dust masks are now known to be ineffective. Another example of this preventative method is the gas mask, which is more efficient than the dust mask. Yet, even gas masks are not highly efficient with respect to microscopic and sub-microscopic microorganisms. Furthermore, they are extremely cumbersome and cannot generally be used during normal day-to-day activities.

Patents such as U.S. Pat. No. 6,844,005 describe electrostatically charged compositions that may be applied externally in the vicinity of the nostril and attract oppositely charged materials that would otherwise be inhaled. However, those compositions simply create an electrostatic field that helps to filter out oppositely charged materials. While this action may offer suitable protection against particles that are inhaled passively, they suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream. Furthermore, actions by the person having those electrostatic compositions in the vicinity of the nostrils can sufficiently displace the offending particles or organisms, especially in such instances as blowing or wiping the nose, so that particles that were held captive by the former compositions could become dislodged, again set free, and be inhaled.

OBJECTS OF THE INVENTION

It is therefore an object of the invention to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method and compositions capable of capturing particulates and microorganisms.

It is another object of the invention to have the capability to hold it for a duration from being dislodged in to the air stream again.

It is a further object of the invention to provide a composition that can be applied near the vicinity of the source of release or to the area around the exterior of and/or slightly inside the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition.

It is yet another object of the invention to provide a composition that can be applied to a filter substrate for improving the substrates ability to trap and hold particulates and microorganisms and to simultaneously inactivate, kill, or render harmless the microorganisms so trapped. Such filter substrate could be placed in the close proximity of the skin near the path of inhalation, near the source of release of such particulates while the inhaler is at a distance or both.

It is still another object of the invention to provide a method of prophylactically preventing or of substantially reducing the risk of infection by an infectious agent without the utilization of ingested antiviral and/or antibacterial agents.

Yet other objects of the invention will be apparent to those of ordinary skill once having benefit of the instant disclosure. In all of the foregoing objects, the deficiencies of the previously mentioned prior art are overcome by the teachings of this invention.

SUMMARY OF THE INVENTION

These and other objects of the invention are unexpectedly achieved by an electrostatically charged composition having at least one polymeric quaternary compound in an aqueous or non-aqueous based formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to anti-microorganism, anti-viral/anti-bacterial products and methods that involve the use of products that restrict the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. Additionally, in the present invention, these electrostatically charged nasal application products are used to hold the contaminants including micro-organisms, viruses, bacteria, and other harmful or toxic particulate outside the body and render them harmless.

Emergencies of Anthrax lead to the concept of avoidance of inhaling airborne microscopic and sub-microscopic contaminants. It is the intention of the Present Invention to filter and render harmless materials such as anthrax spores, human corona virus, smallpox virus, influenza virus, avian flu virus, swine flu virus, rhino virus, and other biological or chemical elements/toxins/irritants, and the like, prior to their entering the nasal passages.

Airborne microorganisms are a major cause of respiratory ailments in humans, causing allergies, asthma, and pathogenic infections of the respiratory tract. Airborne fungal spores are also important agents that spread diseases. Respiratory diseases cause many fatalities and are a cause of great concern. During a sneeze, millions of tiny droplets of water and mucus are expelled at a high velocity. The droplets contain viral particles and/or bacteria. This is a means of transmission of several diseases by inhaled airborne particles as follows:

VIRAL DISEASES (virus type in brackets)	BACTERIAL DISEASES (bacterial name in brackets)
Chickenpox (Varicella)	Whooping cough (*Bordetella pertussis*)
Flu (Influenza)	Meningitis (*Neisseria* species)
Measles (Rubeola)	Diphtheria (*Corynebacterium diphtheriae*)
German measles (Rubella)	Pneumonia (*Mycoplasma pneumoniae*, *Streptococcus* species)
Mumps (Mumps)	Tuberculosis (*Mycobacterium tuberculosis*)
Smallpox (Variola)	Anthrax (*Anthracsis* bacterium)
SARS (Human Corona)	

Diseases caused by environmental particulates include, but are not limited to the following:

ENVIRONMENTAL PARTICULATE DISEASES	SOURCE
Psittacosis (*Chlamydia psittaci*)	Dried, powdery droppings from infected birds (parrots, pigeons, etc.)
Legionnaire's disease (*Legionella pneumophila*)	Droplets from air-conditioning systems, water storage tanks, etc., where the bacterium grows.
Acute allergic alveolitis (various fungal and actinomycete spores)	Fungal or actinomycete spores from decomposing organic matter (composts, grain stores, hay, etc.)
Aspergillosis (*Aspergillus fumigatus*, *A. flavus*, *A. niger*)	Fungal spores inhaled from decomposing organic matter.
Histoplasmosis (*Histoplasma capsulatum*)	Spores of the fungus, in old, weathered bat or bird droppings.
Coccidioidomycosis (*Coccidioides immitis*)	Spores in air-blown dust in desert regions (Central, South and North America) where the fungus grows in the soil.

To accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied, including surfaces such as skin, textile (woven and non-woven), and hard surfaces, such as floors, walls, wood, metal, plastic, etc. The formulation is generally aqueous based, but may include non-aqueous solvents used which are compatible with the other formulation components and the application surface to which it is applied. Preferably, the formulation is an aqueous formulation. In addition to the polyquaternary ammonium compound, the composition includes at least. Furthermore, the composition may contain, but is not required to contain various thickeners, gellants, fragrances, colorants, emollients, humectants, and generally other suitable components that are compatible with the end use application and the other components of the formulations. Thus, a composition of the invention that is intended to be applied to a filter substrate that is perhaps used as a mask with an additional liner between a user and the filter substrate may utilize materials that would not be compatible with direct contact with skin, although it is preferable that all of the components are compatible with direct application to the skin as a means of limiting reaction due to inadvertent contact between the composition and the skin.

A formulation of the invention comprises:

water,

at least one quaternary thickener,

a preservative,
a conditioner,
an emulsifier,
a biocidic agent, and
a neutralizing agent added to adjust and achieve a pH in the range of 5.0 to 6.8.

It may further comprise without limitation a combination of the following:
a surfactant,
a thickener,
an emollient,
a humectant, and
a binder.

In an exemplary embodiment of such a formulation, a quaternary thickener may comprise without limitation, at least one of the following:
Polyquaternium-10
Polyquaternium-22
Polyquaternium-67
Polyquaternium-70
Polyquaternium-72
Polyquaternium-88
Cocodimonium Hydroxypropyl Hydrolyzed Keratin
Hydroxypropyltrimonium Wheat Protein

Benzalkonium Chloride may also serve the same function, but it is also a cationic agent as well as a biocide. Another biocide that may be used is Lysine HCL.

In an exemplary embodiment of such a formulation, an emulsifier may comprise without limitation, at least one of the following:
Cetyl Alcohol (which can also serve as a thickener)
Cetearyl Alcohol
Glyceryl Stearate
Ceteareth-20
PEG-40 Stearate
Dicetyl Phosphate
Ceteth-10 Phosphate

In an exemplary embodiment of such a formulation, the emollient may be Isocetyl Behenate without limitation. The thickener may be Cetyl Alcohol or Stearyl Alcohol without limitation.

In an exemplary embodiment of such a formulation, a preservative may comprise without limitation, at least one of the following:
Phenoxyethanol;
Methylparaben;
Butylparaben;
Ethylparaben;
Propylparaben;
Isobutylparaben.

Examples of typical formulations found to be effective appear in the ten tables that follow. Percentages are given by weight.

TABLE 1

Ingredient	Percent Range	Function
Water	62%-80%	Solvent, Moisturizer
Gluconolactone, Sodium Benzoate	1%	Preservative
Lysine HCL	1%	Conditioner
Polyquaternium - 67	3%-6%	Conditioner
Octoxynol - 9	2%-5%	Surfactant
Polyquaternium - 72	6%-10%	Conditioner
Polyquaternium - 70	0.5%-1%	Conditioner
Dipropylene Glycol Isocetyl Behenate	4%-6%	Emollient
Stearyl Alcohol	1%-3%	Thickener
Cetyl Alcohol	0.25%-1%	Thickener
Ceteareth - 20, PEG - 40 Stearate, Cetearyl Alcohol	1%-2%	Emulsifier
Water, Hydrolyzed Algin	0.5%-1.5%	Conditioner
Hydrolized Soy Protein	0.25%-1%	Conditioner

TABLE 2

Ingredient	Percent Range	Function
Water	72%-88%	Solvent, Moisturizer
Phenoxyethanol Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-6%	Conditioner, Quaternary
Nonoxynol - 10	2%-4%	Surfactant
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetearyl Alcohol, Glyceryl Stearate Emulsifier, PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Cetearyl Alcohol, Dicetyl Phosphate, Ceteth - 10 Phosphate	0.5%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.01%-0.05%	Neutralizing Agent

TABLE 3

Ingredient	Percent Range	Function
Water	67%-87%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-7%	Conditioner, Quaternary
Polyquaternium - 72	3%-7%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolized Keratin	1%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetyl Alcohol	1.5%-2.5%	Thickener
Cetearyl Alcohol, Glyceryl PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.025%-.075%	Neutralizing Agent

TABLE 4

Ingredient	Percent Range	Function
Water	71%-83%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	4%-6%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternum - 88	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	2%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3.5%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.025%-.075%	Neutralizing Agent

TABLE 5

Ingredient	Percent Range	Function
Water	73%-85%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	2%-3%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	2%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.75%	Neutralizing Agent

TABLE 6

Ingredient	Percent Range	Function
Water	69%-85%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben,	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 10	0.25%-0.85%	Conditioner, Quaternary
Polyquaternium - 67	1.5%-3.5%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cetyl Alcohol	1%-3%	Thickener
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.75%	Neutralizing Agent

TABLE 7

Ingredient	Percent Range	Function
Water	67%-86%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-4%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-1.5%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolized Keratin	0.5%-1.5%	Conditioner, Quaternary
Microcare Quat CTC 30	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	3%-5%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 8

Ingredient	Percent Range	Function
Water	58%-74%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	10%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-3%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-1.5%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-1.5%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Polybutene	4%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide

TABLE 8-continued

Ingredient	Percent Range	Function
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.0.05%-0.1%	Neutralizing Agent

TABLE 9

Ingredient	Percent Range	Function
Water	54%-73%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	8%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-4%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Polybutene	3%-4%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 10

Ingredient	Percent Range	Function
Water	52%-71%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	9%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-3.5%	Conditioner, Quaternary
Polyquaternium - 67	1%-3%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Polybutene	5%-6%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 10-continued

Ingredient	Percent Range	Function
Wheat Protein		
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

All of the formulations described in TABLE 1-10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein. The same results may be achieved by varying the percentages for the active and inactive ingredients. Varying the percentages for the active ingredients affects the potency of the formulation. Varying the percentages for the inactive ingredients affects the consistency of the formulation. The desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue experimentation.

I claim:

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

3. The formulation of claim **2** wherein the at least one cationic agent is a polymeric quaternary ammonium compound.

4. The formulation of claim **3** wherein the at least one polymeric quaternary ammonium compound is taken from the group consisting of:

Polyquaternium-10,
Polyquaternium-22,
Polyquaternium-67,
Polyquaternium-70,
Polyquaternium-72, and
Polyquaternium-88.

5. The formulation of claim **2** wherein the at least one cationic agent is Cocodimonium Hydroxypropyl Hydrolyzed Keratin or Hydroxypropyltrimonium Wheat Protein.

6. The formulation of claim **2** wherein the at least one cationic agent is Benzalkonium Chloride.

7. The formulation of claim **2** wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.

8. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:

a) at least one biocidic agent, and

b) at least one quaternary thickener.

9. The formulation of claim **8** wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.

10. The formulation of claim **8** wherein the at least one quaternary thickener is taken from the group consisting of:

Polyquaternium-10,
Polyquaternium-22,
Polyquaternium-67,
Polyquaternium-70,
Polyquaternium-72, and
Polyquaternium-88.

11. The formulation of claim **8** wherein the at least one cationic agent is Cocodimonium Hydroxypropyl Hydrolyzed Keratin or Hydroxypropyltrimonium Wheat Protein.

12. The formulation of claim **8** wherein the at least one cationic agent is Benzalkonium Chloride.

13. The formulation of claim **8** further comprising:

a) water,

b) a preservative,

c) a conditioner, and

d) an emulsifier.

14. The formulation of claim **13** further comprising a neutralizing agent added to adjust a pH in the range of 5.0 to 6.8.

15. The formulation of claim **13** further comprising a surfactant.

16. The formulation of claim **13** further comprising a thickener.

17. The formulation of claim **13** further comprising an emollient.

18. The formulation of claim **13** further comprising a humectant.

19. The formulation of claim **13** further comprising a binder.

20. The formulation of claim **13** wherein the preservative is taken from the group consisting of:

Phenoxyethanol,
Methylparaben,
Butylparaben,
Ethylparaben, and
Isobutylparaben.

21. The formulation of claim **13** wherein the emulsifier is taken from the group consisting of:

Cetyl Alcohol,
Cetearyl Alcohol,
Glyceryl Stearate,
Ceteareth-20,
PEG-40 Stearate,
Dicetyl Phosphate,
Ceteth-10 Phosphate.

22. The formulation of claim **16** wherein the thickener is Cetyl Alcohol or Stearyl Alcohol.

23. The formulation of claim **13** wherein:

a) the amount of water ranges from 54% to 90% by weight

b) the amount of the quaternary thickener ranges from 0.5% to 5.0% by weight,

c) the amount of biocidic agent ranges from 0.25% to 2% by weight,

d) the amount of emulsifier ranges from 0.5% to 4% by weight.

* * * * *

EXHIBIT D

BlueWillow Biologics

Bringing Nanoscience to Life

NanoBio® Protect Nasal Antiseptic Solution

NanoBio® Protect

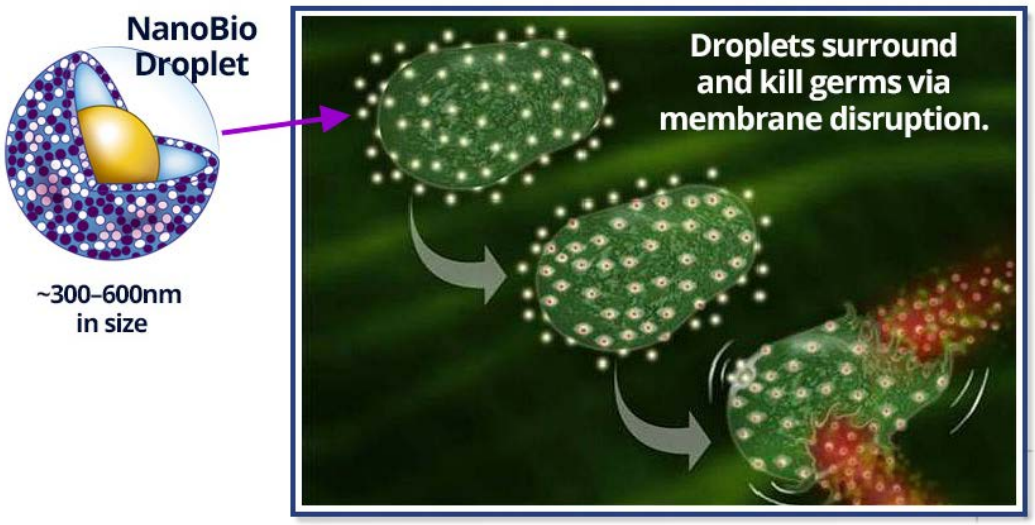
NanoBio® Protect is an alcohol-free nasal antiseptic solution that can be used to help reduce germs on skin that can cause infections. The product is easy to apply with any cotton swab for use on the skin around the rim of your nose as well as the skin up to one-half inch inside each nostril. It is non-irritating, fragrance-free and leaves no residue after application.

NanoBio® Protect is an FDA regulated over-the-counter skin antiseptic that incorporates the active ingredient benzalkonium chloride (BZK), which has been used in humans as a topical skin antiseptic since the 1940's. NanoBio® Protect is similar in concept to a hand sanitizer but is designed for use on the skin inside and around the nose where germs frequently enter the body.

The unique effectiveness of NanoBio® Protectis derived from BlueWillow's patented nanotechnology. NanoBio® Protect places the BZK antiseptic on the surface of nano-droplets, which results in at least four key advantages:

1. The nano-droplets are attracted to germs by electro-kinetic charge and present the BZK in such a way to enable killing of germs on contact,
2. The droplets persist on skin for 4 or more hours, enabling long-lasting effectiveness,
3. The droplets significantly hydrate skin to avoid dryness and cracking that can allow germs in.
4. And lastly, when bound to nano-droplets, BZK is non-irritating to the skin.

NanoBio® Protect kills germs via membrane disruption. NanoBio® Protect is comprised of positively charged droplets that are 300–600nm in size. The droplets are attracted to negatively charged germs in the skin. As shown to the right, the nano-droplets physically disrupt the outer membrane of germs, killing on contact.



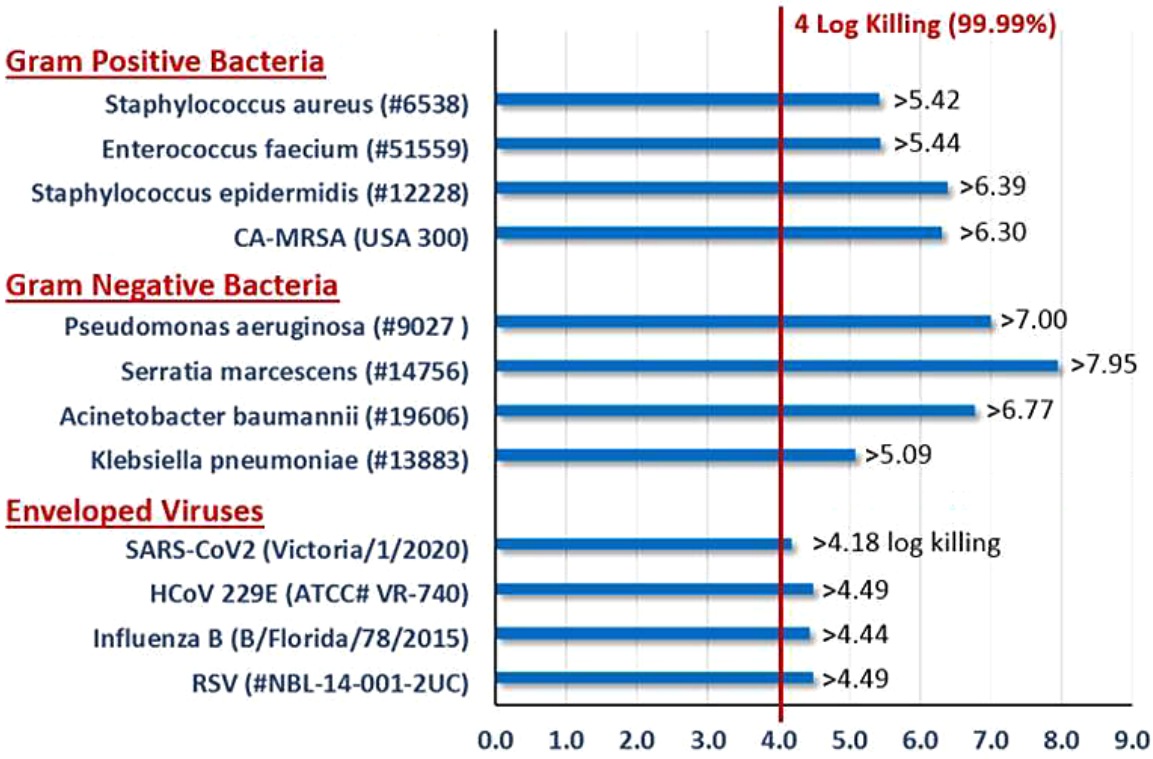
NanoBio® Protect is applied by thoroughly swabbing the skin up to one-half inch inside of each nostril and is recommended for use to help reduce germs on the skin in and around the nose that can cause infections. It should be used in conjunction with frequent handwashing, limited touching of the face, and social distancing to help minimize infection. Each 0.75 oz bottle of NanoBio® Protect will provide 40 or more treatments. A single application should involve the use of two swabs, including one for each nostril, or the use of a double-sided swab.

The product can be applied to the skin every 4–8 hours as needed, and is recommended for use during periods of increased risk of exposure to germs. For example, a healthcare worker might apply NanoBio® Protect two or more times a day. A flight attendant might apply the product 1–2 times during a long flight. Whereas, someone that is mostly staying at home in isolation may only need to apply it once a day or every few days prior to heading to the store or to an appointment.

Scientific Research Behind NanoBio® Protect

BlueWillow's nasal antiseptic

has not been clinically tested to confirm protection against COVID-19 infection in humans. It has



demonstrated both anti-bacterial and anti-viral activity in laboratory tests making it a potentially important additive measure to reduce the risk of infection

Standard *in vitro* lab experiments demonstrate that NanoBio® Protect kills more than 99.99% of germs within 60 seconds of exposure, as shown in the graph to the right.

Recent studies conducted by Public Health England also demonstrate NanoBio® Protect's ability to kill COVID-19 virus in laboratory tests. However, as stated above, studies to test for protection in humans have not yet been performed.

In addition, *ex vivo* tests in human skin (Figure A below) demonstrate that NanoBio® Protect persists on skin up to 7x better than commercial products and aqueous solutions containing the same BZK antiseptic agent. In vivo studies conducted in human volunteers (Figure B below) demonstrate that a single application of NanoBio® Protect significantly increases skin hydration for at least 3 hours, as compared to common hand sanitizer products:

Figure A

Ex vivo levels of BZK (µg/g tissue) in human abdominal skin following one application
(dose of 100 µl/cm², measured at 24 hours)

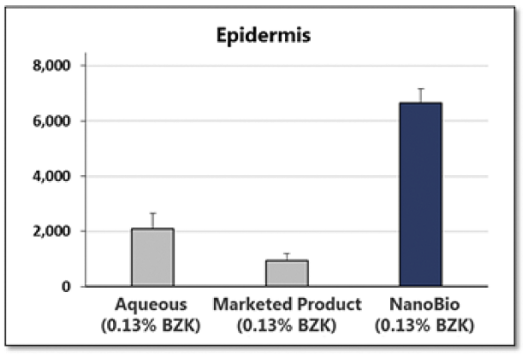
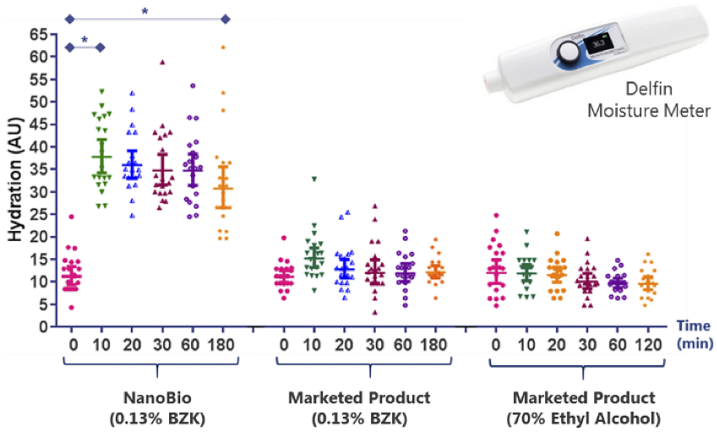


Figure B

Measured following 1mL application to the arms of human volunteers



Safety

NanoBio® Protect and similar NanoBio® formulations have been tested extensively in animal and human studies involving topical application to skin. These studies demonstrate that topical NanoBio® products are non-irritating and are not absorbed systemically. The products are alcohol-free and are comprised of nanodroplets that have been optimized to provide significant advantages when used as topical antiseptic products, without being absorbed through the skin and into the bloodstream.

NanoBio® Protect's active ingredient is 0.13% benzalkonium chloride, which is regulated by the FDA as a skin antiseptic and has been used in humans for over 75 years. Unlike alcohol-based products, NanoBio® Protect does not irritate or dry out the skin, and instead provides a moisturizing and comforting experience. The product should be applied with any cotton swab to the skin around the nose and up to one-half inch inside of each nostril where germs frequently enter the body.

Peer-Reviewed Scientific Publications

Other scientific publications describe the extensive research conducted with topical NanoBio formulations, as listed below:

- *"A Nanoemulsion as an Effective Treatment Against Human Pathogenic Fungi". Therapeutics and Prevention. 2019, Nov/Dec 4:6*
- *"Screening of Nanoemulsion Formulations and Identification of NB-201 as an Effective Topical Antimicrobial for Staphylococcus aureus in a Mouse Model of Infected Wounds". Military Medicine. 2016, May: 181, 5S:259-264*
- *"Nanoemulsion Therapy for Burn Wounds Is Effective as a Topical Antimicrobial Against Gram-Negative and Gram-Positive Bacteria". Burn Care Res. 2016, March /April: 37(2); 104-114*
- *"Treatment With a Novel Topical Nanoemulsion (NB-001) Speeds Time to Healing of Recurrent Cold Sores". Drugs Dermatol. 2012 Aug; 11(8):970-7*
- *"In Vitro Antibacterial Activity of NB-003 against Propionibacterium acnes". Antimicrobial Agents And Chemotherapy, Sept. 2011,Vol. 55, No. 9, p. 4211–4217*
- *"Topical Nanoemulsion Therapy Reduces Bacterial Wound Infection And Inflammation After Burn Injury". Surgery. 2010*
- *"NB-002, A Novel Nanoemulsion With Broad Antifungal Activity Against Dermatophytes, Other Filamentous Fungi, And Candida Albicans". Antimicrobial Agents And Chemotherapy, Aug. 2009, Vol. 53, No. 8, p. 3273–3279*
- *"In Vitro Activities of a Novel Nanoemulsion against Burkholderia and Other Multidrug-Resistant Cystic Fibrosis-Associated Bacterial Species". Antimicrobial Agents And Chemotherapy, Jan. 2009, Vol. 53, No. 1, p. 249–255*
- *"The Fungicidal Activity Of Novel Nanoemulsion (X8W60PC) Against Clinically Important Yeast And Filamentous Fungi". Mycopathologia 155: 195–201, 2001*
- *"A Novel Surfactant Nanoemulsion With A Unique Non-Irritant Topical Antimicrobial Activity Against Bacteria, Enveloped Viruses And Fungi". Microbiol. Res. (200l) 156, l-7*
- *"Inactivation Of Ebola Virus With A Surfactant Nanoemulsion". Acta Tropica 87 (2003) 315/320*
- *"Antimicrobial Mechanism Of Action Of Surfactant Lipid Preparations In Enteric Gram-Negative Bacilli". Journal of Applied Microbiology 2000, 89, 397-403*
- *"Prevention of Murine Influenza A Virus Pneumonitis by Surfactant Nano-emulsions". Antiviral Chemistry & Chemotherapy, 2000, 11:41-49*
- *"A Novel Surfactant Nanoemulsion with Broad-Spectrum Sporicidal Activity Against Bacillus Species". The Journal of Infectious Diseases, 1999, 180:1939–49*

BlueWillow Biologics

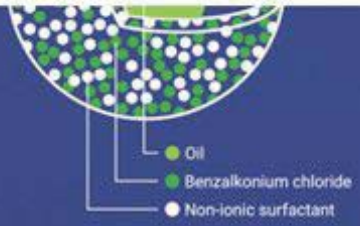
2311 Green Road | Ann Arbor, Michigan 48105

Telephone: 734-302-4000 | Fax: 734-302-9150

EXHIBIT E

Protect

About Where to Buy FAQs Contact Us BUY NOW



earn more about
NanoBio Protect

NanoBio® Protect uses proprietary nanotechnology to deliver a common skin antiseptic in a new way. Learn more about the research behind NanoBio Protect

How is nanotechnology used in NanoBio Protect?

NanoBio Protect works because of its patented nano-formulation. The product's unique, oil-based nanodroplets enhance the antiseptic's antimicrobial activity, optimizing its ability to kill germs on the skin. The nanodroplets are small enough to be effective on the skin, but too large to be absorbed into the bloodstream — creating a layer of lasting protection.

NanoBio Protect adds BZK antiseptic to the surface of nanodroplets. This technology offers four distinct advantages over conventional BZK antiseptics:

- The Nanodroplets optimize the ability of the antiseptic to kill germs.
- The droplets sit on skin after application, enabling protection for up to 8 hours (in lab testing).
- Dry skin allows germs to penetrate. Nanodroplets hydrate the skin, preventing dryness and cracking.
- When bound to the oil-based Nanodroplets, the antiseptic does not irritate the skin.

- When bound to the oil-based Nanodroplets, the antiseptic does not irritate the skin.

Can you provide more detail on how the nano-technology works?

NanoBio Protect is composed of positively-charged droplets that are 300-600nm in size. These droplets are attracted to negatively-charged germs on the skin. The nanodroplets deliver the antiseptic BZK to the surface of the germs where the germ is inactivated via membrane disruption.

Other conventional BZK antiseptics often combine BZK with water, causing crystallization. When crystallization occurs, it rapidly inactivates the antiseptic and can lead to skin irritation. But because each NanoBio Protect droplet carries a positive charge, the droplets repel each other — keeping the BZK molecules separated and preventing crystallization.

Is nano-technology as used in this product safe?

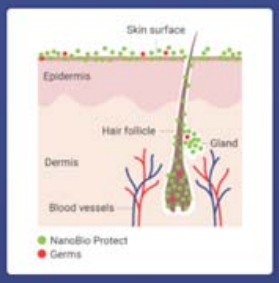
NanoBio® Protect uses proprietary nanotechnology to deliver a common skin antiseptic in a new way.

Effectiveness

The nanodroplets are optimized for size and charge in order to maximize their germ-killing impact. The positively-charged droplets deliver the antiseptic to the negatively-charged germs on the skin, inactivating them via membrane disruption.

Duration

NanoBio Protect's nanodroplets are positively charged, enabling them to stay active on the surface of the skin for significantly longer than common water-based BZK antiseptic solutions.



Safety

NanoBio Protect's nanodroplets are small enough to reach germs that hide in the deep layers of skin, but big enough to prevent absorption through the skin into the bloodstream.